K131555

JAN 3 1 2014

510(K) Summary

Section 5

Submitter: Medsource International, LLC
5346 Shoreline Drive
Mound, MN 55364

Contact Person: Jennifer Ness, Quality and Regulatory Affairs Manager
5346 Shoreline Drive
Mound, MN 55364
Phone: 952-241-8318

Date Prepared: Wednesday, November 06, 2013

General Information:

Common Name: Catheter, intravascular, therapeutic, short-term
Regulatory Reference: 21 CFR §880.5200
Product Code: FOZ
Classification: Class II
Panel: General Hospital
Proprietary Name: MedSource IV Safety Catheter
Single Use: Yes
Sterile: Yes

Indication for Use:

The MedSource IV Safety Catheter is indicated to sample blood or administer fluids intravenously. The MedSource IV Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy appropriateness for the solution being administered and duration of the therapy.

Description of the Device:

The MedSource IV Safety Catheter is a safety medical device used for inserting a catheter into a patient's body for purpose of delivery of fluids or drainage of fluids from the patient's body. This device is engineered to protect healthcare workers using it against accidental needle stick injury and exposure to parts of the device that have come in contact with patient's blood or other body fluids, and have hence been potentially contaminated with infectious agents. In addition this device also secures the needle (used to insert the catheter) in an enclosed chamber, thus protecting healthcare and other personnel from exposure to patient body fluids after the device has been discarded post-use.

The device comprises a sharp needle attached to a hub which projects into a chamber. In the 'unactivated' state prior to insertion, the needle and hub are 'locked' in position. There exists a retraction mechanism for 'unlocking' the needle such that on activation of this mechanism it is withdrawn and completely enclosed within the chamber. This

mechanism for retracting the needle preferably includes a coiled spring or other elastic components. The retraction mechanism is activated by the user using only one hand by means of a lever or 'switch'.

The device is available in six gauges identified also by specific colors.

Model	Description	Gage	Color
MS-84014	IV SAFETY CATHETER: 14 GA X 1.75"(50/BX)	14	Orange
MS-84016	IV SAFETY CATHETER: 16 GA X 1.16"(50/BX)	16	Gray
MS-84018	IV SAFETY CATHETER: 18 GA X 1.16"(50/BX)	18	Green
MS-84020	IV SAFETY CATHETER: 20 GA X 1.16" (50/BX)	20	Pink
MS-84022	IV SAFETY CATHETER: 22 GA X 1"(50/BX)	22	Blue
MS-84024	IV SAFETY CATHETER: 24 GA X .75" (50/BX)	24	Yellow

Description of the Device Design:
The MedSource IV Safety Catheter is substantially equivalent to the Becton Dickinson Angiocath Autogaurd (K984059)

Comparison Point	Predicate Devices	Result of Comparison
Intended Use	Becton Dickinson Angiocath Autogaurd (K984059)	Substantially equivalent
Technological Characteristics (Materials of Construction, Dimensions, Performance in)	Becton Dickinson Angiocath Autogaurd (K984059)	Materials of construction-same or similar Performance-minor variations Dimensions-minor variations
Instructions for Use	Becton Dickinson Angiocath Autogaurd (K984059)	Very similar

Summary of Performance Testing Characteristics:

	Submission Device ↓	**Predicate Device ↓**
Comparison Point ↓	MedSource IV Safety Catheter	Becton Dickinson Angiocath Autogaurd (K984059)
	Chemical Tests	
Volatile Residue	<15.0mg	<15.0mg
Heavy Metals	<1ppm	<1ppm
Residue on Ignition	<5.0mg	<5.0mg
Buffering Capacity	Complies to USP-34	Complies to USP-34
	Biological Tests	

Sterility	Sterile ETO	Sterile ETO
Physical Tests		
Integrity	Complies to ISO 10555-1 and ISO10555-5	Complies to ISO 10555-1 and ISO10555-5
Flow-rate	14G: 300 ml/min 16G: 220 ml/min 18G: 105 ml/min 20G: 65ml/min 22G: 35ml/min 24G: 20ml/min	14G: 300 ml/min 16G: 220 ml/min 18G: 105 ml/min 20G: 65ml/min 22G: 35ml/min 24G: 20ml/min
Tensile	18G: 10N 20G: 5N 22G: 5N 24G: 3N	18G: 10N 20G: 5N 22G: 5N 24G: 3N

Conclusion:

As shown by data in the table above, there are no significant performance specification differences between the MedSource IV Safety Catheter and the substantially equivalent device. Therefore, we conclude that the performance specifications demonstrate that the Subject Device is as safe, as effective, and performs as well as or better than that of the legally marketed predicate device.

Reference Documents:

1. ISO 10555-5: Sterile, single use intravascular catheters
2. ISO 11607-1/2 Packaging for terminally sterilized medical devices
3. BS EN 868-5 Packaging materials and systems for medical devices which are to be sterilized. Heat and self-sealable pouches and reels of paper and plastic film construction-Requirements and test methods
4. DIN 58953-6 "Sterilization paper for bags and tubing pickings ".Testing for germ proof ness in moisture with passage of air
5. ASTM F 2054 Standard test method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates.
6. ASTM F 1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packages
7. ASTM D638 Plastic Tensile Testing
8. ISO 10993: Part 10 Biological evaluation of medical devices: Test of irritation and skin sensitization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

MedSource International, LLC
Ms. Jennifer Ness
Manager, Quality Control and Regulatory Affairs
5346 Shoreline Drive
Mound, MN 55318

Re: K131555
Trade/Device Name: MedSource IV Safety Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 23, 2013
Received: December 16, 2013

Dear Ms. Ness:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

SECTION 4

510(k) Number: K131555
Device Common Name: Catheter, intravascular, therapeutic, short-term
Device Proprietary Name: MedSource IV Safety Catheter
Indications for Use: The MedSource IV Safety Catheter is indicated to sample blood, or administer fluids intravenously. The MedSource IV Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy appropriateness for the solution being administered and duration of the therapy.

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ☐ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Digitally signed by
Richard C. Chapman
Date: 2014.01.30
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